3. 510(k) Summary of Safety and Effectiveness

MAR 7 2013

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92(c).

510(k) Owner:	Micro Therapeutics d/b/a ev3 Neurovascular 9775 Toledo Way Irvine, CA 92618 Establishment Registration No. 2029214
Contact Person:	Analia Staubly Regulatory Affairs Specialist Telephone: (949) 680-1201 E-mail: Analia.Staubly@covidien.com
Date Summary Prepared:	February 26, 2013
Trade Name of Device:	SilverSpeed™ Hydrophilic Guidewire Mirage™ Hydrophilic Guidewire X-celerator™ Hydrophilic Guidewire X-pedion™ Hydrophilic Guidewire
Common Name of Device:	Hydrophilic Guidewire
Classification of Device:	Primary 21 CFR 870.1330 Guide, Wire, Catheter, Neurovasculature MOF, Class II Secondary 21 CFR 870.1330 Guidewire, Catheter DQX, Class II
Predicate Device:	Micro Therapeutics, Inc. d/b/a ev3 Neurovascular, SilverSpeed™ Hydrophilic Guidewire — K982543, K993257 X-celerator™ Hydrophilic Exchange Guidewire — K010497 Originally, cleared under trade name: SilverSpeed™ Hydrophilic Guidewire X-pedion™ Hydrophilic Guidewire — K001454 Originally, cleared under trade name: SilverSpeed™ Hydrophilic Guidewire Mirage™ Hydrophilic Guidewire — K002212

Device Description:

The Hydrophilic Guidewire is a stainless steel guidewire with a radiopaque, platinum distal coil. The guidewire is hydrophilically coated on the distal portion. For the X-celerator™ Hydrophilic Guidewire labeled as an "Exchange" guidewire, the proximal portion is coated with polytetrafluoroethylene (PTFE). The Exchange guidewire facilitates the exchange of one interventional device for another, while maintaining guidewire position in the anatomy.

The following modifications have been made to the device:

- Change in the degree of polymerization with the base coat material.
- Elimination of Brown Oxide pigment from base coat material.

Intended Use:

The Hydrophilic Guidewire is indicated for general intravascular use to aid in the selective placement of catheters in the peripheral, visceral and cerebral vasculature during diagnostic and/or therapeutic procedures.

Non-Clinical Performance Data:

The following tests were performed to support the changes to the Hydrophilic Guidewires:

Biocompatibility Testing

- USP Physiochemical Extraction
- Cytotoxicity: ISO MEM Elution Using L-929 Mouse Fibroblast Cells
- Sensitization: ISO Guinea Pig Maximization Sensitization Test
- ISO Intracutaneous Reactivity Test
- ISO Acute Systemic Injection Test
- Material Mediated Rabbit Pyrogen Test
- ASTM Hemolysis Assay – Direct Contact Method
- Complement Activation C3a and SC5b-9 Assay
- Four Hour Thromboresistance Evaluation in Dogs

Bench Testing

- Visual Inspection
- Tip Buckling (Flexibility)
- Tip Shapeability
- Tip Retention
- Coating Adherence
- Friction Test
- Torque Response

Shelf-life Testing

- 36-month Accelerated Aging

In addition, no clinical or animal testing was performed as there is no change in the indications for use or the fundamental scientific technology of the device.

Substantial Equivalence Determination	The information presented in the 510(k) shows that the Hydrophilic Guidewires are substantially equivalent to the predicate devices previously in regards to the identical indications for use, device design, similar device materials, device dimensions, and materials comprising its accessories and final packaging, and design specifications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 7, 2013

Micro Therapeutics, Inc. d/b/a ev3 Neurovascular
Analia Staubly
Regulatory Affairs Specialist
9775 Toledo Way
Irvine, California 92618

Re: K124007
Trade/Device Name: SilverSpeed™, Mirage™, X-celerator™ Exchange, and X-pedion™ Hydrophilic Guidewires
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: MOF, DQX
Dated: December 21, 2012
Received: December 26, 2012

Dear Ms. Staubly:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Victor Krauthamer -S

Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K124007

Device Name: SilverSpeed™, Mirage™, X-celerator™ Exchange , and X-pedion™ Hydrophilic Guidewires

Indications For Use:

The SilverSpeed™, Mirage™, X-celerator™ Exchange , and X-pedion™ Hydrophilic Guidewires are indicated for general intravascular use to aid in the selective placement of catheters in the peripheral, visceral and cerebral vasculature during diagnostic and/or therapeutic procedures.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Victor Krauthamer -S
2013.03.05 18:38:20 -05'00'

(Division Sign Off)
Division of Neurological and Physical Medicine Devices (DNPMD)

510(k) Number ___K124007___